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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,504	12/19/2005	Julia Cianci	Q88025	6545

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EXAMINER	
PESELEV, ELLI	
ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
09/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,504	CIANCI ET AL.	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7-9,11-28,30-32 and 37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 7-9, 11-28, 30-32 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1, 7-9, 11-28, 30-32 and 37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for tobramycin prodrugs having structural formulae as set forth in Tables 2-4 on pages 47-61 of the specification, does not reasonably provide enablement for any aminoglycoside, linker group and a pharmacokinetic regulator attached at any position on an aminoglycoside antibiotic. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

(A) The breadth of the claims.

The claims encompass an enormous number of possible prodrugs of tobramycins.

(B) The state of the prior art.

Shechter et al (J. Med. Chem. 2002, 45, 4264-4270) disclose N-[2-sulfo-0-9-fluorenylmethoxycarbonyl]3-gentamicin C1 prodrug.

(C) The level of predictability in the art.

The art of making specific prodrugs which have the desired properties and activity is highly unpredictable.

(D) The existence of working examples.

The working examples are limited to a number of specific tobramycin prodrugs set forth in Tables 2-4 of the specification.

(E) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Because there is no way to predict a priori which other prodrugs, besides those specifically disclosed, will produce tobramycin having desired property and/or activity, it would take an enormous amount of trial and error to test various prodrugs encompassed by the present claims.

Applicant's arguments filed July 11, 2008 have been fully considered but they are not persuasive.

Applicant contends that in view of the specification when read as a whole, one of ordinary skill in the art would be able to practice the invention over the scope claimed without undue experimentation. This argument has not been found persuasive. The present claims still encompass an enormous number of compounds having significant differences in structural formula. A person having ordinary skill in the art at the time the claimed invention was made would have expected that such significant differences would lead to unpredictable results. For example, a claimed compound wherein L is an oxime containing 20 carbon atoms and Y is a monosaccharide would not be expected to have similar properties a the claimed compound wherein L is an ester containing two carbon atoms and Y is a substituted starch having 20 carbon atoms or a substituted peptide containing 20 amino acids.

Claims 20 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention.

(A) The breadth of the claims.

The terminology "therapeutic ingredients" (claim 20) encompasses all therapeutic agents having any activity such as anti-cancer agents, immune suppressing agents, anti-viral agents, anti-inflammatory agents, etc.

The terms "antimicrobial" and "antiinfective" (claim 21) encompass all possible infection, including viral infections.

(B) The state of the prior art.

Tobramycins are known antibacterial agents. The combination of tobramycins with agents such as anti-viral agents is not known in the prior art.

(C) The existence of working examples.

The working examples are limited to anti-bacterial compounds.

(D) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Because there is no way to predict a priori , in combination with which other therapeutic, antimicrobial or antiinfective ingredients the claimed compositions would be useful, it would take an undue amount of experimentation to test the claimed compositions for their biological activity.

Applicant's arguments filed July 11, 2008 have been fully considered but they are not persuasive.

Claim 20 still encompasses any therapeutic agent and claim 21 still encompasses a compound having any anti-infective activity, such as anti-viral compound or an anti-parasitic compound.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev
/Elli Peselev/
Primary Examiner, Art Unit 1623